UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

TEIKOKU PHARMA USA, INC.,
1718 Ringwood Avenue
San Jose, California 95131; and

TEIKOKU SEIYAKU CO., LTD.,
567 Sanbonmatsu, Higashikagawa,
Kagawa 769-2695 Japan,

Defendants.

Case Number: 16-1440

FILED
APR 07 2016
MICHAEL E. KUNZ, Clerk
By_____Dep Clerk

STIPULATED ORDER FOR PERMANENT INJUNCTION

Plaintiff, the Federal Trade Commission ("Commission"), filed its Complaint for Injunctive and Other Equitable Relief in this matter pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants Teikoku Pharma USA, Inc. and Teikoku Seiyaku Co., Ltd., by their respective attorneys, have reached an agreement to resolve this case through settlement, and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Order for Permanent Injunction and Final Judgment ("Order") to resolve all matters in dispute between them in this action.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over the parties and the subject matter of this action. Teikoku Defendants have stipulated that, for purposes of this Order alone, the Court has personal jurisdiction over them.

2. Venue for this matter is proper in this Court under Sections 5(a) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a), 53(b).

3. The Complaint charges that Teikoku Defendants engaged in anticompetitive acts that constitute an unfair method of competition in violation of Sections 5(a) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a) and 53(b), by entering an agreement that foreclosed competition from generic equivalents of the brand-name drug Lidoderm® for a period of time.

4. Teikoku Defendants neither admit nor deny any of the allegations in the Complaint, except that Teikoku Defendants admit the facts necessary to establish the personal and subject matter jurisdiction of this Court.

5. The Commission and Teikoku Defendants have agreed to stipulate to entry of this Order to resolve the litigation between them.

6. Teikoku Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees in this action.

7. Teikoku Defendants waive all rights to appeal or otherwise challenge or contest the validity of this Order.

8. Teikoku Defendants stipulate that they shall comply with the provisions of this Order pending its entry by the Court.

9. Entry of this Order is in the public interest.

DEFINITIONS

For purposes of this Order, the following definitions apply:

1. "Commission" means the United States Federal Trade Commission.

2. "TPU" means Teikoku Pharma USA, Inc., any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by TPU, their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.

3. "Teikoku Seiyaku" means Teikoku Seiyaku Co., Ltd., any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by Teikoku Seiyaku, their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.

4. "Teikoku Defendants" means TPU and Teikoku Seiyaku.

5. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 355(b)(2).

6. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 355(j).

7. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and marketed, sold, or distributed in the United States under a name other than the proprietary name identified in the NDA.

8. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.

9. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

10. "Branded Subject Drug Product" means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

11. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

12. "Control" or "Controlled" means the holding of more than fifty percent (50%) of the common voting stock or ordinary shares in, or the right to appoint more than fifty percent (50%) of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

13. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

14. "FTC Investigation" means the pre-complaint investigation conducted by FTC staff under File No. 141-0004.

15. "FTC Litigation" means any legal proceeding brought by the Commission that alleges the Lidoderm Settlement and License Agreement violates the law(s) enforced by the Commission.

16. "Generic Filer" means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.

17. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.

18. "Lidoderm Settlement and License Agreement" means the Settlement and License Agreement entered into on or about May 28, 2012, by and between Endo Pharmaceuticals Inc., Teikoku Defendants, and Watson Laboratories, Inc. relating to Lidoderm®.

19. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.

20. "NDA Holder" means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug Product in the United States.

21. "No-AG Commitment" means any agreement with, or commitment or license to, a Generic Filer that restricts, delays, imposes a condition precedent upon, or otherwise interferes with the research, development, manufacture, regulatory approval, marketing or sale of an Authorized Generic.

22. "Patent Infringement Claim" means any allegation threatened in writing or included in a complaint filed with a court of law, that a Generic Product may infringe any U.S. Patent held by, or licensed to, an NDA Holder.

23. "Payment by the NDA Holder to the Generic Filer" means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 60 day period starting 30 days before executing a Brand/Generic Settlement Agreement and ending 30 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payments by the NDA Holder to the Generic Filer:

a. compensation for saved future litigation expenses not to exceed a maximum limit, which is initially set at seven million dollars ($7,000,000) and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411--5411--) published by the Bureau of Labor Statistics of the United States Department of Labor, or its successor;

b. provisions in a Brand/Generic Settlement Agreement providing a date after which a Generic Filer can begin selling, offering for sale, or distributing the Subject Drug Product;

c. provisions in a Brand/Generic Settlement Agreement that permit a Generic Filer to begin selling, offering for sale, or distributing the Subject Drug Product once another drug company begins selling, offering for sale, or distributing the Subject Drug Product;

d. an agreement to settle or resolve a different litigation claim, so long as that separate agreement independently complies with the terms of this Order (including the timing provisions above); and

e. continuation or renewal of a pre-existing agreement so long as: (i) the pre-existing agreement was entered at least 90 days before the relevant Brand/Generic Settlement Agreement; (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement; and (iii) entering the continuation or renewal is not expressly contingent on agreeing to a Brand/Generic Settlement.

24. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.

25. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in part, modifications, or extensions thereof.

ORDER

I. Prohibited Agreements

IT IS ORDERED that:

A. From the date Teikoku Defendants sign this Order, Teikoku Defendants, individually and collectively, are prohibited from entering into any Brand/Generic Settlement that includes: (1) Payment by the NDA Holder to the Generic Filer; and (2) an agreement by the

Generic Filer not to research, develop, manufacture, market, or sell the Subject Drug Product for any period of time,

provided, however, that Teikoku Defendants may enter into any written agreement that receives the prior approval of the Commission. Within thirty (30) days of receiving a request for prior approval under this paragraph, the Director of the Bureau of Competition (or his or her designee) shall consider the request in good faith and shall notify Teikoku Defendants in writing whether Commission staff believes the relevant agreement raises issues under Section 5 of the FTC Act and the reasons for such a belief, or this Order shall be deemed not to preclude the requesting party from entering into the subject written agreement.

II. Reporting Requirements

IT IS FURTHER ORDERED that:

A. Teikoku Defendants shall submit to the Commission a verified written report setting forth in detail the manner and form in which they have complied and are complying with this Order:

1. Within sixty (60) days after entry of this Order, and

2. On the first anniversary of entry of this Order, and annually thereafter for nine (9) years.

B. Teikoku Defendants shall include with each verified written report required by this provision a copy of any additional agreement with a party to a Brand/Generic Settlement to which a Teikoku Defendant is also a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional

agreement is entered within a year of executing the Brand/Generic Settlement Agreement, *provided that*, Teikoku Defendants do not need to submit any additional agreement that they submitted to the Commission with a prior verified written report required by this provision; and

C. Teikoku Defendants shall submit each report or notification required under this paragraph to the Secretary of the Commission and shall send an electronic copy of each report to the Compliance Division of the Bureau of Competition of the Commission at bccompliance@ftc.gov.

D. This Order does not alter the reporting requirements of Teikoku Defendants pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

III. Change of Corporate Control

IT IS FURTHER ORDERED that:

A. Teikoku Defendants shall notify the Commission at least thirty (30) days prior to:

1. Any proposed dissolution of Teikoku Defendants;

2. Any proposed, acquisition, merger, or consolidation of Teikoku Defendants; or

3. Any other change in Teikoku Defendants, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

B. Teikoku Defendants shall submit any notice required under this paragraph to the Secretary of the Commission and shall send an electronic copy of the notification to the

Compliance Division of the Bureau of Competition of the Commission at bccompliance@ftc.gov.

IV. Access to Information

IT IS FURTHER ORDERED that

A. For the purpose of determining or securing compliance with this Order, subject to any legally recognized privilege, and upon written request with reasonable notice to any Teikoku Defendant, Teikoku Defendants shall permit any duly authorized representative of the Commission:

1. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of a Defendant reasonably related to this Order, which copying services shall be provided at the request of the authorized representative(s) of the Commission and at the expense of Teikoku Defendants; and

2. To interview a reasonable number of officers, directors, or employees of Teikoku Defendants, who may have counsel present, regarding any such matters.

V. FTC Litigation

IT IS FURTHER ORDERED that, in connection with any FTC Litigation, Teikoku Defendants shall:

A. Agree to service of process of all Commission subpoenas issued under Rule 45 of the Federal Rules of Civil Procedure;

B. Respond to the Commission's requests for production of documents as though Teikoku Defendants were parties to the FTC Litigation, and shall limit objections to those available to a party to such litigation.

C. Upon reasonable notice, make up to three (3) of their officer(s), director(s), agent(s), or employee(s), or corporate representative(s) designated under Federal Rule of Civil Procedure 30(b)(6), available for deposition at a mutually agreed upon location in the continental United States;

D. Refrain from objecting to any document request on the grounds that the requested documents are not located in the United States;

E. Not object on grounds of timeliness to any motion(s) to compel the production of documents that Teikoku Defendants withheld as privileged or protected by the work product doctrine during the FTC Investigation; and

F. Negotiate in good faith with the Commission to provide a declaration, affidavit, and/or sponsoring witness, if necessary, to establish the authenticity and admissibility of any documents and/or data that Teikoku Defendants produce or have produced to the Commission. Any sponsoring witness provided to the Commission under this paragraph will not count towards the three (3)-witness limitation in sub-paragraph V.C.

VI. Retention of Jurisdiction

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

VII. Expiration of Order

IT IS FURTHER ORDERED that this Order shall expire twenty (20) years after the date it is entered.

VIII. Dismissal and Costs

This action shall be dismissed with prejudice as to Teikoku Defendants. Each party shall bear its own costs.

SO ORDERED this 6th day of April, 2016.

Hon.

UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

Date: 3/28/16

Markus H. Meier
Assistant Director
Health Care Division
Bureau of Competition
Federal Trade Commission

FOR TEIKOKU PHARMA USA, INC.:

Date: Feb. 14, 2016

Ichiro (Paul) Mori
President and CEO

Date: Feb. 16, 2016

Joseph A. Meckes
Squire Patton Boggs (US) LLP
COUNSEL FOR TEIKOKU PHARMA USA, INC.

FOR TEIKOKU SEIYAKU CO., LTD:

M. Fujioka

Date: Feb. 15, 2016

Misako Fujioka
President and CEO

Date: Feb. 16, 2016

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